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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,825	07/22/2003	Anatoly E. Martynyuk	UF-281D2	7782
29847	7590	03/17/2006	EXAMINER	
BEUSSE BROWNLEE WOLTER MORA & MAIRE 390 N. ORANGE AVENUE SUITE 2500 ORLANDO, FL 32801			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,825

Applicant(s)

MARTYNYUK ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 14-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' Response under 37 CFR 1.111 filed December 15, 2005 is acknowledged. The Examiner regrets the inadvertent lack of clarity with respect to claim 35 that was newly presented at the time of the last Office Action. As stated on page 2 of the last Office Action, lines 9-10, claims 1-13 and 35 were under consideration. Claims 14-34 remain withdrawn from consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 1-13 and 35 remain under consideration.

A new title and Abstract are noted.

In response to the provisional obviousness-type double patenting rejections of claims 1-13 that were set forth in the last Office Action, Applicants have elected to hold these issues in abeyance.

Accordingly, these rejections of record are maintained.

Claims 6 and 7 were rejected in the last Office Action under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. It was asserted the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. The specification fails to define the actual compounds contemplated that are "facilitating substances".

Applicants again argue substances capable of facilitating transport across the blood-brain barrier were known as of the filing date of the subject application.

The Examiner is in agreement that substances capable of facilitating transport across the blood-brain barrier were known as of the filing date of the subject application.

However, this one definition of a “facilitating substance” is directed to what certain compounds in the claimed pharmaceutical composition do, instead of what they actually are.

For the reasons of record, and because claims 6 and 7 are drawn to functional characteristics, rather than structural characteristics, of the components of the claimed “article of manufacture”, the rejection under 35 U.S.C. 112, first paragraph, is maintained.

Claims 1-13 were rejected under 35 U.S.C. 103 as being unpatentable over Liechty et al., Journal of Nutrition. It was asserted Liechty teaches the intravenous administration of an aromatic amino acid infusion (Aminosyn RF) comprising phenylalanine, tyrosine and tryptophan in a pharmaceutically acceptable carrier or diluent. Commercial formulations are known to comprise both isomers.

Applicants argue the inclusion of high concentrations of a broad variety of amino acids materially changes the nature of the composition in that large neutral amino acids *likely would* interfere with the desired transport of aromatic amino acids across the blood-brain barrier.

Applicants’ argument is not found persuasive. Independent claims 1 and 35 are not limited to an administration involving transport across the blood-brain barrier. Further, claim 1 recites “at least one”. Therefore, the inclusion of a single aromatic amino acid and a pharmaceutically acceptable carrier or diluent meets all limitations of claim 1. Liechty teaches administration of an independent infusion comprising the aromatic amino acid L-tyrosine, as glycyl-L-tyrosine. The attachment of the glycine

radical may be considered a facilitating substance in the context of Liechty's teaching. It acts as a "carrier" of the amino acid. See Figure 1 or 2, page 1165. Written instructions, as part of the packaging of a pharmaceutical preparation, as required by claims 4 and 5, are conventional.

The rejection of claims 1-10 under 35U.S.C. 103 is maintained for the reasons of record. The rejection of claims 11-13 is withdrawn.

Claims 1, 2, 4, 5, 8-13 and 35 were rejected in the last Office Action under 35 U.S.C. 102(b) as being anticipated by Liechty et al., Journal of Nutrition. It was asserted Liechty teaches a pharmaceutical composition comprising aromatic amino acids and a pharmaceutically acceptable carrier or diluent for infusion.

Applicants argue Liechty does not teach desirability to remove certain amino acids from the Aminosyn composition.

Liechty teaches administration of an independent infusion comprising the aromatic amino acid L-tyrosine, as glycyl-L-tyrosine. See Figure 1 or 2, page 1165. Written instructions, as part of the packaging of a pharmaceutical preparation, as required by claims 4 and 5, are conventional. Independent claims 1 and 35 merely require the presence of "at least one aromatic amino acid".

Accordingly, the rejection of record of claims 1, 2, 4, 5, 8-10 and 35 is maintained. The rejection of claims 11-13 is withdrawn.

In the last Office Action claims 1, 8-13 and 35 were rejected under 35 U.S.C. 102(b) as being anticipated by The Merck Index. Page 1253 discloses a known commercial product, an artificial sweetener, comprising L-phenylalanine. Page 1669

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discloses a known use for L-tryptophan as a probe for studying protein structure and dynamics. Page 1677 discloses a known use for L-tyrosine as a probe for studying protein structure and dynamics.

Applicants argue a pharmaceutically acceptable carrier is not disclosed.

A pharmaceutically acceptable carrier may or may not be required for the disclosed utility for L-tryptophan and L-tyrosine as probes for studying protein structure and dynamics; however, a pharmaceutically acceptable carrier is well known in the commercial product in which L-phenylalanine is used as an artificial sweetener.

Accordingly, the rejection of claims 1, 8, 9, 13 and 35, of record, under 35 U.S.C. 102(b), is maintained.

Claims 9, 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Dependent claims 9, 11 and 13 lack clarity due to the recitation "at least one aromatic amino acid is an admixture." Alternatively, since an admixture appears to be intended, the recitation "at least one aromatic amino acid is an admixture of" should be deleted in claims 9, 11 and 13 and replaced with -- wherein said admixture is --.

No claim is allowed.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 14, 2006

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**PHYLLIS SPIVACK
PRIMARY EXAMINER**